



INTERNATIONAL
BOTTLED WATER
ASSOCIATION

August 20, 2002
(Via Messenger)
Submitted in Duplicate

Documents Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Docket No. 98N-0359
Rockville, MD 20852

Re: [Program Priorities in the Center for Food
Safety and Applied Nutrition,
Docket No. 98N-0359]

Dear Sir:

The International Bottled Water Association (IBWA) appreciates the opportunity to submit comments to the U.S. Food and Drug Administration (FDA or Agency) on the June 21, 2002, *Federal Register* notice requesting input for the establishment of program priorities in the Center for Food Safety and Applied Nutrition (CFSAN) for FY2003. IBWA has noted and appreciates that FDA has two bottled water goals designated as B plus level priorities on the 2002 CFSAN Program Priorities List. These include revising the radionuclides quality standard for bottled water, and developing a proposal to revise the bottled water quality standard for arsenic.

IBWA is the authoritative source of information about all types of bottled waters. Founded in 1958, IBWA member companies account for approximately 80 percent of bottled water sold and distributed in the U.S. IBWA's membership includes U.S. and international bottlers, distributors and suppliers. IBWA is committed to working with FDA, which regulates bottled water as a packaged food product, and state governments, in concert with the IBWA Model Code, to set stringent bottled water standards to help ensure safe, high quality products.

Overall, IBWA requests that FDA place the following two bottled water items on CFSAN's A list for Program Priorities for 2003: (1) implementation of a standard of microbiological quality for total coliform; and (2) implementation of a standard of quality for uranium. In addition, IBWA requests that a standard of quality for arsenic, and a standard of quality for nine compounds monitoring requirements for bottled water be included on the CFSAN B list for 2003. IBWA's detailed comments are as follows.



98N-0359

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1. Standard of Microbiological Quality for Total Coliform: IBWA requests that FDA implement a standard of microbiological quality for total coliform for bottled water on the A list for CFSAN's Program Priorities for 2003. FDA began the rulemaking process for total coliform in 1993 and has included it in years past as one of the CFSAN B priorities in its annual Priority List notice. However, it was not included as a priority for CFSAN in 2002.

IBWA recommends the adoption of a total coliform standard for bottled water of "No *Escherichia coli* detectable in a 100ml portion/sample. No validated total coliform detectable in a 100 ml portion/sample as substantiated by retesting." IBWA recommends that FDA adopt the above mentioned standard which the Agency has supported as an international standard for the Codex Alimentarius Commission. The public health will benefit by the adoption of a standard on total coliform. The detection of *E. coli* is an indicator of the potential presence of harmful pathogens. Although pathogens are rarely present in groundwater, the establishment of a uniform FDA coliform standard for microbiological quality will help ensure the absence of pathogens in bottled water and further enhance consumer trust in the product.

2. Standard of Quality for Uranium: IBWA requests that FDA place implementation of a standard of quality for uranium for bottled water on the A list for CFSAN's Program Priorities for 2003. Under 21 U.S.C. §349, the Secretary of U.S. Department of Health and Human Services (HHS) is required to review any regulation of a drinking water contaminant by the U.S. Environmental Protection Agency (EPA) and rule on its applicability to bottled water 180 days before the implementation of the standard by EPA for public drinking water systems. Without the adoption of an FDA standard of radiological quality for uranium, bottled water producers will be subject to a new system for testing, monitoring and analysis for uranium based on EPA test protocols for public water systems that is substantially different from the current FDA radionuclides standards for bottled water. A standard of 30 µg/L for uranium for bottled water will be required by December 7, 2003, and FDA must make a decision by June 7, 2003 as required by law. If FDA fails to promulgate a bottled water standard by this date, EPA's monitoring requirements will be applied to bottled water. FDA should maintain the current annual monitoring and compliance determination provisions for radionuclides by promulgating a uranium standard no later than December 7, 2003.

As background, FDA has already issued a standard of quality for bottled water for three radionuclides, except uranium. These radionuclides include: Combined Radium-226/228 – 5 pCi/L; Adjusted Gross Alpha – 15 pCi/L, not including radon or uranium; and, Beta Particle and Photon Radioactivity – 4 millirems/year. These standards are the same as the EPA standards [21 CFR §165.110(b)(5)].

However, the FDA annual monitoring and compliance determination provisions apply to these standards, but not to uranium because of the lack of a uranium standard for bottled water. IBWA recommends that FDA adopt a new 30 µg/L standard of radiological quality for uranium in bottled water promptly. In promulgating this standard, FDA should maintain the current annual monitoring and compliance determination provisions that are currently in place for the other radionuclides [21 C.F.R. §129.80(g)(2)]. The FDA annual monitoring system for radionuclides has worked well for a number of years and has proven to be protective of public health.

3. Standard of Quality for Arsenic: IBWA requests that FDA place implementation of a standard of quality for arsenic for bottled water on the B list for CFSAN's Program Priorities for 2003. Specifically, FDA is urged to adopt an arsenic standard of quality of 10 ppb for bottled water with an effective date as early as possible. In addition, FDA should also maintain the same annual monitoring frequency and the process for compliance determinations that are currently in place for bottled water under 21 CFR§128.80(g)(2). The procedure to accomplish the revised arsenic standard for bottled water will be to revise the current standard of 50 ppb through rule making by FDA. IBWA has already lowered the Association's Model Code standard of quality for arsenic to 10 ppb, with an effective date of January 1, 2002.

4. Standard of Quality for Nine Compounds Monitoring Requirements: IBWA requests that FDA place implementation of a standard of quality for nine compounds monitoring requirements for bottled water on the B list for CFSAN's Program Priorities for 2003. IBWA is recommending that FDA formally establish an annual frequency of testing for nine specific compounds. Specifically, FDA should either: (1) modify the monitoring requirements for four specific compounds (diquat, endothall, glyphosate, and dioxin) from 6 samples every three years to one sample annually, in conformance with all other FDA good manufacturing practice requirements for bottled water; or (2) release a guidance document outlining FDA's requirements for all of the nine compounds, as suggested in the agency's notice dated August 6, 1998, published in the *Federal Register*.


The EPA version of the nine compounds rule required that public water systems monitor for the four contaminants listed above for four consecutive quarters once every three years. By allowing the "Hammer Provision" of the Safe Drinking Water Act Amendments of 1996 to take effect, the same monitoring frequency was required for bottled water. However, the EPA standard provides for reduced monitoring (annual) when it is proven that the compounds are not found in a specific public water system. As of December 31, 2001, after three years of monitoring in accordance with the August 6, 1998 notice, none of the four contaminants have been detected in IBWA members' bottled water products. This demonstrates that continued monitoring, although costly, will exhibit no

IBWA – FDA Comments for Docket No. 98N-0359
August 20, 2002
Page 4 of 4

benefit to the protection of public health. IBWA is simply requesting the monitoring tests be conducted annually.

Thank you in advance for your consideration of IBWA's comments. If you have any questions, about IBWA's comments, please do not hesitate to contact me or Cindy Yablonski, IBWA Vice President of Research, Science and Technical Affairs at (703) 683-5213.

Sincerely,


Joseph Doss
President